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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,728

10/27/2006

Hikaru Matsuda

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23117 7590 07/14/2009
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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

07/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,728	Applicant(s) MATSUDA ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 6,7 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/18/2008;01/31/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-5,8-23 as they relate to a non-myocardial stem cell in the reply filed on 06/30/2009 is acknowledged.

Claims 6-7 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/30/2009.

Claims 1-26 are pending. Claims 1-5 and 8-23 are under consideration in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,8-18 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/07568 (published 02/01/2001) as evidenced by Carnac, G et al (1998, **Mol. Biol. Cell.**, 9:1891-1902.)

The claims are very broadly written. Claim 1 is drawn to a three dimensional structure applicable to heart comprising a cell derived from a part other than myocardium of an adult. The only structural limitation in the body of the claim is “a cell derived from a part other than myocardium of an adult”. Furthermore, the term “derived” is broadly interpreted. Thus, as the preamble is given little patentable weight, and as a cell or cell colony, is a three-dimensional structure, any non-myocardial cell meets the limitations of the claim 1. The elected invention is drawn to a ‘stem cell’ as opposed to a differentiated cell. Claim 16 and 17 fails to differ in scope from claim 1. The recitation of “applicable to heart” and “applicable to myocardium” are intended uses and are not given patentable weight.

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Regarding claims 11 and 12, the claims require expression of “at least one non-adult heart marker”. This phrase appears unclear in light of the fact that the cells are derived from an adult (claim 1). However, the specification at paragraph 193 of the PG PUB corresponding to the instant application clarifies this phrase as meaning and “adult non-heart marker” or “non-adult-heart marker. Thus, the claim is interpreted as referring to markers of adult non-heart cells.

Recitation of the term “medicament” in claims 22 and 23 is in the preamble and is interpreted as an intended use. The medicament is not required to have any additional elements over those recited in any one of claims 1-21.

‘568 taught a method of preparing transplantable skeletal myoblast cells and fibroblast cells cultured on a surface coated with Poly-L-lysine and laminin (page 2, lines 18-24). Myoblasts and fibroblasts are cells that derive from more potent stem cells as required by claim 8. Myoblast cells were derived from nonmyocardial tissue (skeletal muscle biopsy) of an adult human (page 38) and applied to dogs, meeting the limitations of claim 10. Syngeneic transplant was used as well meeting the limitations of claim 9 (page 41, 43). Skeletal myoblasts inherently express markers including myogenin, MyoD and Myf5 (see Carnac et al, 2002). CD56 and the myosin chain genes are also inherently expressed in myoblasts (claim 13). Because the cells are skeletal myoblasts, the marker would be expressed at levels of at least 50% and 100% of that of skeletal myoblasts as required by claims 12,14 and 15.

Claims 1-5,8,11-17 and 19-23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,207,451 (March 27, 2001) as evidenced by Carnac, G et al (1998, **Mol. Biol. Cell.**, 9:1891-1902).

The claims are very broadly written. Claim 1 is drawn to a three dimensional structure applicable to heart comprising a cell derived from a part other than myocardium of an adult. The only structural limitation in the body of the claim is “a cell derived from a part other than myocardium of an adult”.

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Furthermore, the term “derived” is broadly interpreted. Thus, as the preamble is given little patentable weight, and as a cell or cell colony, is a three-dimensional structure, any non-myocardial cell meets the limitations of the claim 1. The elected invention is drawn to a ‘stem cell’ as opposed to a differentiated cell. Claim 16 and 17 fails to differ in scope from claim 1. The recitation of “applicable to heart” and “applicable to myocardium” are intended uses and are not given patentable weight.

Regarding claims 11 and 12, the claims require expression of “at least one non-adult heart marker”. This phrase appears unclear in light of the fact that the cells are derived from an adult (claim 1). However, the specification at paragraph 193 of the PG PUB corresponding to the instant application clarifies this phrase as meaning and “adult non-heart marker” or “non-adult-heart marker. Thus, the claim is interpreted as referring to markers of adult non-heart cells.

Recitation of the term “medicament” in claims 22 and 23 is in the preamble and is interpreted as an intended use. The medicament is not required to have any additional elements over those recited in any one of claims 1-21.

‘451 teaches a three-dimensional myoblast containing structure consisting of a rolled sheet of myoblasts (col.6-7). Myoblasts and fibroblasts are cells that derive from more potent stem cells as required by claim 8. Myoblast cells were derived from nonmyocardial tissue (limb skeletal muscle) of rat (col. 6). Skeletal myoblasts inherently express markers including myogenin, MyoD and Myf5 (see Carnac et al, 2002). CD56 and the myosin chain genes are also inherently expressed in myoblasts (claim 13). Because the cells are skeletal myoblasts, the marker would be expressed at levels of at least 50% and 100% of that of skeletal myoblasts as required by claims 12,14 and 15.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/

Primary Examiner, Art Unit 1632